DENTAL IMAGINEERS
& ASSOCIATES
Concept, Development & Production
of Specialized Dental Technology

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K013808

JAN 3 0 2002

510(k) Summary

Nov.10, 2001

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Phone: (732) 493-4747
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Device/Trade Name: SleepBite (proposed)

Descriptive Name: Mandibular Advancement Device (MAD)

Common Name: Anti-snoring Device

Classification Name: Device, Anti-snoring

Substantial Equivalence Devices: The SleepBite appliance is substantially equivalent to the Elastic Mandibular Appliance, also referred to as EMA, K971724. It is also substantially equivalent to the Silent Nite appliance, K972424.

Description: SleepBite is a double plate mandibular advancement device that is adjustable via a calibrated advancement screw. The screw is located on the anterior segment of the lower plate and extends slightly between the lips. A small adjustment wrench is used to turn the screw, and thereby, it allows the mandible to be anteriorized relative to the maxilla. The clinician can determine the magnitude of the advancement via a calibrated scale which part of the screw itself. The scale is marked in 2mm units.

The connectors between the upper and lower plates are flexible elastomeric tubes that have the ability to remain sufficiently rigid to permit the advancement of the mandible while they also allow complete lateral motion. It also allows the mandible to open sufficiently to permit oral breathing. The dental plates can be made of thin ethylene vinyl acetate sheets or dental acrylic so that the appliance will not impinge on freeway space.

Intended Use: Sleep Bite is prescribed for the patient by the healthcare professional.

A. Sleep Bite is indicated for use in patients with benign snoring, when snoring is not accompanied by sleep apnea.

B. Sleep Bite is indicated for use in patients with snoring, when medically prescribed following the appropriate testing for obstructive sleep apnea.

C. Sleep Bite is indicated for patients who suffer from sleep bruxism concomitant with benign snoring.

Technological Characteristics: SleepBite, Silent Nite and EMA are all dual plate appliances in which the upper and lower plates are connected by flexible connectors that hold the mandible in an advanced position. With the predicate devices the adjustment of the appliance is made be selecting the appropriate length connector in order to hold the mandible in the most effective posture to open the airway. The appliances are supplied with a kit of connectors of various sizes. The clinician must remove these appliances from the mouth in order to secure the connector. The Silent Nite requires a special plier to attach the connector to the structure.

The difference in SleepBite is that it has an anterior adjustment screw that (a) enables the clinician to serial advance the mandible in small increments, (b) visualize the magnitude of the adjustment at the same time, and (c) this can be done by turning the screw while the patient is wearing the appliance.

There are differences in the vertical/diagonal direction of the connectors. Both EMA and Silent Nite have connector which go from the posterior of the lower plate to the anterior of the upper plate and attached to small buttons on the buccal aspect of the plates. The SleepBite connector attaches to the upper posterior plate in the first molar area on the buccal side of the acrylic plate, while the other terminal end attaches to the rigid wire connection arm of the anterior screw. All of these connectors enable the devices to advance the mandible by reciprocal action.

Conclusion: SleepBite is appropriate for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2002

Mr. William A. Belfer
President
Dental Imagineers & Associates
804 West Park Avenue
Ocean, New Jersey 07712

Re: K013808
Trade/Device Name: SleepBite
Regulation Number: None
Regulation Name: Device, Anti-Snoring
Regulatory Class: Unclassified
Product Code: LRK
Dated: November 11, 2001
Received: November 15, 2001

Dear Mr. Belfer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013808

510(k) Number (if known):_____

Device Name: SleepBite

Indications For Use:

SleepBite is prescribed for the patient by the healthcare professional.

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013808

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)